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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,234	04/06/2000	TSUTOMU AWAMURA	49668(281)	1287

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EXAMINER

WHITE, EVERETT NMN

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/529,234

Applicant(s)

AWAMURA ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on December 18, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/529,234 is acceptable and a CPA has been established. An action on the CPA follows.
2. The amendment filed December 18, 2002 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claim 12 has been canceled.
  - (B) Claims 1, 4, 8 and 11 have been amended.
  - (C) Comments regarding Office Action have been provided drawn to
    - (i) 102(b) rejection, which has been withdrawn.
    - (ii) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.
3. Claims 1-11 are pending in the case.
4. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1-11, the term "soluble film" is vague since it is not stated in the claims if the film is water soluble, alcohol soluble, alkaline soluble or soluble in some other type of liquid or substance, which renders all the claims indefinite.

In Claims 1 and 2, the term "solid solution" is not clear since one is not able to ascertain whether the claim is referring to a solid or solution. This term renders claims 1

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and 2 indefinite. Claims 3-11 are also rejected since Claims 3-11 are dependent from Claims 1 and 2 and this term is not clarified in these claims.

In Claim 7, the term "saccharide" lacks clear antecedent basis by depending from Claims 1 or 2, which renders the claim indefinite.

6. Applicant's arguments with respect to Claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

7. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (US Patent No. 4,136,145, already of record) in view of Tapolsky et al (US Patent No. 5,800,832, newly cited) or Burns et al (US Patent No. 6,294,202, newly cited).

Applicants claim a soluble film preparation for oral administration comprising a drug, an edible polymer and a monosaccharide or an oligosaccharide, wherein the film is obtained by spreading and drying and has an elution rate of more than about 50% per 10 minutes and the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer. Additional limitations include weight percent of the content of the drug, edible polymer, and monosaccharide or oligosaccharide in the soluble film preparation; and recitation of specific drugs, edible polymers, and oligosaccharides.

The Fuchs et al patent discloses admixtures of medicament and carriers in the form of a film wherein the active substance is incorporated therein (see abstract). See column 2, 5<sup>th</sup> and 6<sup>th</sup> paragraph for a list of active medicament compounds that may be incorporated into the film. The medicament compounds disclosed in the Fuchs et al patent embrace the drug set forth in the instantly claimed invention. The Fuchs et al patent also indicates the presence of film forming polymers that are known in the art, which include poly-N-vinyl-pyrrolidone, methyl-cellulose, ethyl-cellulose, hydroxyalkyl ethers of cellulose such as hydroxypropyl-cellulose and hydroxy-ethyl-cellulose (see the first paragraph of column 3). Fuchs et al further discloses fillers that may be included with the film that may be selected from lactose, dextrose, starches and mannitol (see

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column 3, 4<sup>th</sup> paragraph). The above listed film forming polymer and fillers of the Fuchs et al patent embrace the edible polymer, monosaccharide, oligosaccharide or maltose starch syrup of the instantly claimed invention. The Fuchs et al patent discloses that the proportion of pharmaceutically active ingredients in the film may be from a pharmaceutically effective trace amount up to about 60% by weight of the film, which covers the amount of drug set forth in instant Claim 2. The Fuchs et al patent also discloses 6-20% by weight of the film-forming polymer and up to 30% by weight of a filler, which is within the range of the amount of edible polymer and monosaccharide or oligosaccharide that is set forth in instant Claim 2. The Fuchs et al patent discloses medicinally active substances that may be admixed in a film (see column 2, lines 60-64). The film preparation set forth in the instantly claimed invention differs from the film of the Fuchs et al patent by reciting in the claims specific compounds, including sulfamethizole and chloramphenicol, which are not set forth in the Fuchs et al patent. The Tapolsky et al patent, which discloses bioerodable films for delivery of pharmaceutical compounds to mucosal surfaces, teaches that the incorporation of pharmaceutical components in films (delivery device) is well known in the art (see abstract). See column 7, lines 55 and 59 whereby Tapolsky et al discloses sulfamethizole and chloramphenicol as examples of chemotherapeutic drugs that can be incorporated in a film.

The instantly claimed film preparation also differs from the Fuchs et al and Tapolsky et al patent by claiming that the film has an elution rate of more than about 50% per 10 minutes. This claimed property of a film appears to be an inherent feature for water-soluble films that comprise similar components and comparable amounts of a drug, edible polymer, and monosaccharide or oligosaccharide, which has been demonstrated in the Fuchs and Tapolsky et al patents. The Burns et al patent, which discloses compositions that comprise bioabsorbable polymers and drugs (see title and column 5, 3<sup>rd</sup> paragraph) that can be prepared in the form of films, further confirms the inherency of this feature by teaching that water soluble films lose their structural integrity as a film after 3 minutes, and become totally dispersed within 20 minutes (see column 6, 3<sup>rd</sup> paragraph).

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One of ordinary skill in this art would be motivated to combine the teachings of the Fuchs et al, Tapolsky et al, and Burns et al patents in a rejection of the instant claims under 35 U.S.C. 103 since each patent discloses compositions in the form of water-soluble films that comprising a pharmaceutical component incorporated into the film.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the active substances that may be incorporated into the film of the Fuchs et al patent with sulfamethizole or chloramphenicol, in view of the recognition in the art, as evidence by the Tapolsky et al patent, that the pharmaceutical compounds remains at the application site while the film dissolves over a period of time, with natural bodily fluids slowly dissolving and eroding away the carrier. Also, one of ordinary skill in this art would have known that the elution rate of the soluble film that is set forth as a limitation in the instant claims is an inherent property of soluble films as demonstrated by the Burns et al patent.

8. Applicant's arguments with respect to Claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

### ***Summary***

9. All the claims are rejected.

### ***Examiner's Telephone Number, Fax Number, and Other Information***

10. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

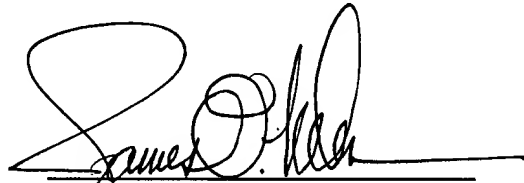
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*  
E.White

  
James O. Wilson  
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